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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., and BRECKENRIDGE PHARMACEUTICAL, INC.,** **Defendants.**	**C.A. No. 2:17-cv-03387-ES-JAD** **(Filed Electronically)**

DEFENDANTS HETERO LABS LIMITED, HETERO LABS LIMITED UNIT V, HETERO DRUGS LIMITED, AND HETERO USA, INC.S' ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Hetero Labs Limited, Hetero Labs Limited Unit V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Celgene Corporation ("Celgene"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiff's Complaint except those expressly admitted below.

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from the Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs"), Nos. 210236 ("Hetero's ANDA"), 210249 ("Aurobindo's ANDA"), 210164 ("Apotex's ANDA"), 210275 ("Mylan's ANDA"), and 210111 ("Breckenridge's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's POMALYST® drug products prior to the expiration of United States Patent Nos. 8,198,262 (the "'262 patent"), 8,673,939 (the "'939 patent), 8,735,428 (the "'428 patent"), and 8,828,427 (the "'427 patent"), all owned by Celgene (collectively, "the patents-in-suit").

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Celgene's Complaint purports to assert an action for patent infringement based in part on Hetero's filing of Abbreviated New Drug Application ("ANDA") No. 210236 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic pomalidomide capsules prior to the expiration of United States Patent Nos. 8,198,262 (the "'262 patent"), 8,673,939 (the "'939 patent), 8,735,428 (the "'428 patent"), and 8,828,427 (the "'427 patent"). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of paragraph 1 of the Complaint and therefore denies them.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions, including cancer. Celgene is a world leader in the treatment of many such diseases, including cancer.

Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 2 of the Complaint and therefore denies them.

3. On information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

ANSWER: Admitted.

4. On information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar - 509301, Andhra Pradesh, India.

ANSWER: Admitted.

5. On information and belief, Hetero Unit-V is a division of Hetero Labs.

ANSWER: Admitted.

6. On information and belief, Defendant Hetero Drugs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

ANSWER: Admitted.

7. On information and belief, Defendant Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Hetero admits that Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. All remaining allegations of paragraph 7 are denied.

8. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Drugs and the U.S. regulatory agent of Hetero Labs and Hetero Unit-V.

ANSWER: Hetero admits that Hetero USA acted as a regulatory agent of Hetero Unit V with respect to ANDA No. 210236. Hetero admits that Hetero Labs is a parent corporation of Hetero USA. Hetero admits that Hetero Unit V is a division of Hetero Labs. Hetero denies all remaining allegations of paragraph 8.

9. On information and belief, Defendant Aurobindo Pharma Limited is a company organized and existing under the laws of India, having a principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad - 500038, Telangana, India.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 9 of the Complaint and therefore denies them.

10. On information and belief, Defendant Eugia Pharma Specialties Limited is a company organized and existing under the laws of India, having a principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad - 500038, Telangana, India.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 10 of the Complaint and therefore denies them.

11. On information and belief, Eugia is a direct subsidiary of Aurobindo Ltd.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 11 of the Complaint and therefore denies them.

12. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 12 of the Complaint and therefore denies them.

13. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 13 of the Complaint and therefore denies them.

14. On information and belief, Aurobindo Ltd. and Eugia, directly or through their subsidiaries, including Aurobindo USA, sell and market pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 14 of the Complaint and therefore denies them.

15. On information and belief, Defendant Aurolife Pharma LLC is a corporation existing under the laws of the State of Delaware, having a principal place of business 2400 Route 130 North, Dayton, New Jersey 08810, and is a wholly owned subsidiary of Defendant Aurobindo USA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 15 of the Complaint and therefore denies them.

16. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 16 of the Complaint and therefore denies them.

17. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 17 of the Complaint and therefore denies them.

18. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 18 of the Complaint and therefore denies them.

19. On information and belief, Apotex Corp. is the authorized U.S. agent for Apotex Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 19 of the Complaint and therefore denies them.

20. On information and belief, Defendant Mylan N.V. is a corporation organized and existing under the laws of Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. On information and belief, the Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 20 of the Complaint and therefore denies them.

21. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 21 of the Complaint and therefore denies them.

22. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, Pennsylvania 15317.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 22 of the Complaint and therefore denies them.

23. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 23 of the Complaint and therefore denies them.

24. On information and belief, Mylan Inc. is a wholly owned subsidiary of Mylan, N.V.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 24 of the Complaint and therefore denies them.

25. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Florida, having a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, FL 33487.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 25 of the Complaint and therefore denies them.

The Patents-in-Suit

26. On June 12, 2012, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '262 patent, entitled, "Methods for treating multiple myeloma using 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '262 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '262 patent is attached to the Complaint at Exhibit A; that the '262 patent is entitled "Methods for treating multiple myeloma using 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione"; that the issue date identified on the cover of the '262 patent is June 12, 2012; that the '262 patent identifies on its face Jerome B. Zeldis as the alleged inventor; and that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '262 patent. Hetero denies that the '262 patent was "duly and lawfully issued," and further denies any remaining allegations of paragraph 26 of the Complaint.

27. On March 18, 2014, the USPTO duly and lawfully issued the '939 patent, entitled, "Methods for treating multiple myeloma with 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '939 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '939 patent is attached to the Complaint at Exhibit B; that the '939 patent is entitled "Methods for

treating multiple myeloma using 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione"; that the issue date identified on the cover of the '939 patent is March 18, 2014; that the '939 patent identifies on its face Jerome B. Zeldis as the alleged inventor; that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '939 patent. Hetero denies that the '939 patent was "duly and lawfully issued," and further denies any remaining allegations of paragraph 27 of the Complaint.

28. On May 27, 2014, the USPTO duly and lawfully issued the '428 patent, entitled, "Methods for treating multiple myeloma with 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '428 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '428 patent is attached to the Complaint at Exhibit C; that the '428 patent is entitled "Methods for treating multiple myeloma using 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione"; that the issue date identified on the cover of the '428 patent is May 27, 2014; that the '428 patent identifies on its face Jerome B. Zeldis as the alleged inventor; that according to the electronic assignment database of the USPTO website, Celgene Corporation is identified as the assignee of the '428 patent. Hetero denies that the '428 patent was "duly and lawfully issued," and further denies any remaining allegations of paragraph 28 of the Complaint.

29. On September 9, 2014, the USPTO duly and lawfully issued the '427 patent, entitled, "Formulations of 4-amino-2-(2,6-dioxopiperidine-3-YL)isoindoline-1,3-dione," to Celgene as assignee of the inventors Anthony Tutino and Michael T. Kelly. A copy of the '427 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '427 patent is attached to the Complaint at Exhibit D; that the '427 patent is entitled "Formulations of

4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione"; that the issue date identified on the cover of the '428 patent is September 9, 2014; that the '427 patent identifies on its face Anthony Tutino and Michael T. Kelly as the alleged inventors; that according to the electronic assignment database of the USPTO website Celgene is identified as the assignee of the '427 patent. Hetero denies that the '427 patent was "duly and lawfully issued," and further denies any remaining allegations of paragraph 29 of the Complaint.

The POMALYST® Drug Product

30. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for pomalidomide capsules (NDA No. 204026), which it sells under the trade name POMALYST®. POMALYST® is an FDA-approved medication used for the treatment of multiple myeloma.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies New Drug Application ("NDA") No. 204026 in connection with POMALYST® (pomalidomide) capsules, and further identifies "CELGENE CORP" as the holder of NDA No. 204026. Hetero further admits that according to labeling approved by FDA in June 2016 states that "POMALYST is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy." All remaining allegations are denied.

31. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

32. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to POMALYST®.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '262, '939, '428, and '427 patents are listed in the electronic Orange Book in connection with POMALYST® (pomalidomide) capsules. Hetero denies any remaining allegations contained in paragraph 32 of the Complaint.

33. The labeling for POMALYST® instructs and encourages physicians, pharmacists, and other healthcare workers and patients to administer POMALYST® according to one or more of the methods claimed in the patents-in-suit.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. Further answering, the labeling speaks for itself. To the extent an answer is required, denied.

Jurisdiction and Venue

34. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that this Court has subject matter jurisdiction over Celgene's claims for infringement under only 35 U.S.C. § 271(e)(2)(A). Hetero denies that this Court has subject matter jurisdiction over any claims for infringement asserted by Celgene under 35 U.S.C. § 271(a), (b), or (c). Hetero denies any remaining allegations contained in paragraph 34 of the Complaint.

35. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no response is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District.

Personal Jurisdiction: Hetero

36. This Court has personal jurisdiction over Hetero USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Hetero USA's principal place of business is in Piscataway, New Jersey. On information and belief, Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0400362826. On information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Hetero USA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction in this District for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 36.

37. On information and belief, Hetero USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Hetero's ANDA. On information and belief, Hetero USA also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 37.

38. This Court has personal jurisdiction over Hetero Labs, Hetero Drugs, and Hetero Unit-V because, *inter alia*, they have: (1) purposely availed themselves of the privilege

of doing business in New Jersey, including directly or indirectly through their subsidiary, agent, and/or alter ego, Hetero USA, a company with its principal place of business in New Jersey; and (2) maintain extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations in paragraph 38.

39. This Court has personal jurisdiction over Hetero because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Hetero intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 39.

40. On information and belief, Hetero USA, Hetero Labs, Hetero United-V, and Hetero Drugs work in concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 40.

41. On information and belief, Hetero USA acts at the direction, and for the benefit, of Hetero Labs, Hetero Unit-V, and Hetero Drugs, and is controlled and/or dominated by Hetero Labs, Hetero Unit-V, and Hetero Drugs.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purposes of this action only. Hetero denies all remaining allegations in this paragraph.

42. On information and belief, Hetero Drugs, Hetero Labs, Hetero Unit-V, and Hetero USA operate as a single integrated business. Hetero Drug's website notes that "Hetero's fully vertical integration of products and services ensures most cost-competitive supply of pharmaceutical APIs and finished dosage products." http://heteroworld.com/pages/why-hetero/. On information and belief, Hetero Drugs and Hetero Labs share common corporate directors.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 42.

43. Hetero Drug's website states that "[w]ith a portfolio of more than 200 marketed products and 150 ANDAs filed across major therapeutic areas, the company is also the largest supplier of anti-retroviral drugs." https://heteroworld.com/pages/business-generics/.

ANSWER: Admitted.

44. On information and belief, Hetero USA, Hetero Labs, Hetero Unit-V, and Hetero Drugs have all previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.*, Civil Action No. 15-161 (JBS)(KMW) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Drugs); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 16-2442 (MLC)(TJB) (D.N.J.) (Hetero USA and Hetero Labs); and *BTG Int'l Ltd., et al. v. Actavis Labs. FL, Inc., et al.*, Civil Action No. 15-5909 (KM)(JBC) (D.N.J.) (Hetero USA, Hetero Labs, Hetero Unit-V).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Hetero does not contest personal jurisdiction solely for the limited purpose of this action only. Hetero denies all remaining allegations of paragraph 44.

Personal Jurisdiction: Aurobindo

45. This Court has personal jurisdiction over Aurobindo USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Aurobindo USA's principal place of business is in East Windsor, New Jersey. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100921223. On information and belief, Aurobindo USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003120. On information and belief, Aurobindo USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Aurobindo USA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 45 of the Complaint and therefore denies them.

46. On information and belief, Aurobindo USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Aurobindo's ANDA. On information and belief, Aurobindo USA also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 46 of the Complaint and therefore denies them.

47. This Court has personal jurisdiction over Aurolife by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Aurolife's principal place of business is in Dayton, New Jersey. On information and belief, Aurolife is registered with the State of New Jersey's Division of Revenue and Enterprise

Services as a business operating in New Jersey under Business Id. No. 0600322732. On information and belief, Aurolife is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003810. On information and belief, Aurolife purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Aurolife.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 47 of the Complaint and therefore denies them.

48. On information and belief, Aurolife is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Aurobindo's ANDA. On information and belief, Aurolife also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 48 of the Complaint and therefore denies them.

49. This Court has personal jurisdiction over Aurobindo Ltd. and Eugia because, *inter alia*, they have: (1) purposely availed themselves of the privilege of doing business in New Jersey, including directly or indirectly through their subsidiaries, agents, and/or alter egos, Aurobindo USA and Aurolife, companies with principal places of business in New Jersey; and (2) maintain extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Aurobindo USA and Aurolife.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 49 of the Complaint and therefore denies them.

50. This Court has personal jurisdiction over Aurobindo because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Aurobindo intends a future course of conduct that includes acts of patent infringement in New

Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 50 of the Complaint and therefore denies them.

51. Aurobindo Ltd.'s Annual Report 2015-16 states that its "US formulation business contributed 55% to [its] overall formulation revenue during the year," and that "Aurobindo received 49 final approvals from the US FDA during the financial year, which helped add to [its] momentum and market presence." *See* Aurobindo Ltd. Annual Report 2015-16 ("Aurobindo Annual Report"), at 38, available at http://www.aurobindo.com/docs/annual-reports/aurobindo-AR-2016-final.pdf. The Aurobindo Annual Report further states that "Aurobindo had been ranked #7 generics supplier" in the United States as of March 2016 and that its "long-term growth strategies being put into action include: [d]eveloping a broad portfolio of DMFs/ANDAs" and "[b]ecoming a significant player in the generics market, especially in the regulated markets with differentiated products." *Id*. at 48.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 51 of the Complaint and therefore denies them.

52. Aurobindo USA's website (http://www.aurobindousa.com/about-us/our-story/) states that "Aurobindo Pharma USA, Inc. (Aurobindo) is a generic solid dosage, small molecule manufacturer, and a wholly owned subsidiary of Aurobindo Pharma Limited."

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 52 of the Complaint and therefore denies them.

53. Aurolife's website (http://www.aurolifepharma.com/aboutus.html) states that "Aurolife is a 100% owned subsidiary of Aurobindo Pharma USA Inc." Its website further notes that "Aurolife is also in the process of constructing a large facility at Dayton, New Jersey to cater for the storage and distribution of drugs for Aurobindo group of companies in USA." *Id.* If further notes that "[t]he [Aurobindo group's] flag ship company, Aurobindo Pharma Ltd . . . is an Indian based, multinational company, with headquarters in Hyderabad, India" and that "Aurolife is exclusively created to address the US pharmaceutical manufacturing needs and to address market opportunities." *Id.*

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 53 of the Complaint and therefore denies them.

54. On information and belief, Aurobindo Ltd., Eugia, Aurobindo USA, and Aurolife work in concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 54 of the Complaint and therefore denies them.

55. On information and belief, Aurobindo USA, Aurolife, and Eugia act at the direction, and for the benefit, of Aurobindo Ltd., and are controlled and/or dominated by Aurobindo Ltd.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 55 of the Complaint and therefore denies them.

56. On information and belief, Aurobindo Ltd. and Aurobindo USA have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g.*, *AstraZeneca AB, et al. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 13-7298 (MLC)(TJB) (D.N.J.); *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 14-6890 (JBS)(KMW) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 56 of the Complaint and therefore denies them.

57. Aurolife has admitted that it is subject to personal jurisdiction in this Judicial District. *See, e.g.*, *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 14-6890 (JBS)(KMW) (D.N.J.), Dkt. No. 9, ¶ 10.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 57 of the Complaint and therefore denies them.

58. Aurobindo USA and Aurobindo Ltd have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See Aurobindo Pharma USA Inc., et al. v. Apicore US LLC, et al.*, Civil Action No. 16-3358 (RMB)(KMW) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 58 of the Complaint and therefore denies them.

59. Aurobindo Ltd. has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g., Aurobindo Pharma Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 16-5079 (MLC)(TJB) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 59 of the Complaint and therefore denies them.

Personal Jurisdiction: Apotex

60. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. Apotex Corp. is registered with the State of New Jersey as a drug wholesaler, under Registration No. 5003192. On information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Apotex Corp.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 60 of the Complaint and therefore denies them.

61. On information and belief, Apotex Corp. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical

products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Apotex's ANDA. On information and belief, Apotex Corp. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 61 of the Complaint and therefore denies them.

62. This Court has personal jurisdiction over Apotex Inc. because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Apotex Corp., a company registered with the State of New Jersey as a drug wholesaler; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Apotex Corp.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 62 of the Complaint and therefore denies them.

63. This Court has personal jurisdiction over Apotex because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Apotex intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 63 of the Complaint and therefore denies them.

64. On information and belief, Apotex Corp. and Apotex Inc. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 64 of the Complaint and therefore denies them.

65. On information and belief, Apotex Corp. acts at the direction, and for the benefit, of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 65 of the Complaint and therefore denies them.

66. On information and belief, Apotex Inc. and Apotex Corp. have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., AstraZeneca AB, et al. v. Apotex Corp., et al.*, Civil Action No. 15-8492 (FLW)(DEA) (D.N.J.); *Bausch & Lomb Inc., et al. v. Apotex Inc., et al.*, Civil Action No. 15-3879 (NLH)(JS) (D.N.J.); *Novartis Pharm. Corp. v. Apotex Inc., et al.*, Civil Action No. 15-3634 (SDW)(LDW) (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc., et al.*, Civil Action No. 15-2384 (PGS)(TJB) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 66 of the Complaint and therefore denies them.

67. Apotex Inc. and Apotex Corp. have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g., Apotex Inc. v. Shire LLC*, Civil Action No. 08-3598 (SRC)(MAS) (D.N.J.); *Apotex Inc., et al. v. Pharmaceutical Resources, Inc.*, Civil Action No. 06-1153 (JLL)(MF) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 67 of the Complaint and therefore denies them.

Personal Jurisdiction: Mylan

68. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On

information and belief, Mylan Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100214277. On information and belief, Mylan Pharmaceuticals is registered with the State of New Jersey's Department of Health as a wholesaler and manufacturer under Registration No. 5003762. On information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Mylan Pharmaceuticals.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 68 of the Complaint and therefore denies them.

69. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Mylan's ANDA. On information and belief, Mylan Pharmaceuticals also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 69 of the Complaint and therefore denies them.

70. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Mylan Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100971292. On information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Mylan Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 70 of the Complaint and therefore denies them.

71. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Mylan's ANDA. On information and belief, Mylan Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 71 of the Complaint and therefore denies them.

72. This Court has personal jurisdiction over Mylan N.V. because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Mylan Pharmaceuticals and Mylan Inc., companies registered with the State of New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Mylan Pharmaceuticals and Mylan Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 72 of the Complaint and therefore denies them.

73. This Court has personal jurisdiction over Mylan because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Mylan intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 73 of the Complaint and therefore denies them.

74. Mylan N.V.'s website (http://www.mylan.com/en/company/corporate-governance) states that "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 74 of the Complaint and therefore denies them.

75. Mylan N.V.'s Form 10-K Annual Report for the Period Ending 12/13/2016 ("Mylan Annual Report") states that on February 27, 2015, "Mylan Inc. became an indirect wholly owned subsidiary of Mylan N.V., and Mylan Inc.'s common stock ceased trading on the NASDAQ." *See* Mylan Annual Report at 53. The Mylan Annual Report further states that "Mylan N.V. is the successor to Mylan Inc." *Id.* at 55.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 75 of the Complaint and therefore denies them.

76. On information and belief, Mylan Pharmaceuticals, Mylan Inc., and Mylan N.V. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 76 of the Complaint and therefore denies them.

77. On information and belief, Mylan Pharmaceuticals acts at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and is controlled and/or dominated by Mylan N.V. and Mylan Inc.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 77 of the Complaint and therefore denies them.

78. On information and belief, Mylan Inc. and Mylan Pharmaceuticals have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 14-7094 (JBS)(JS) (D.N.J.) (Mylan Pharmaceuticals); *Astrazeneca AB, et al. v.*

Mylan Pharmaceuticals Inc., et al., Civil Action No. 13-4022 (MLC)(DEA) (D.N.J.) (Mylan Pharmaceuticals and Mylan Inc.); *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 10-5954 (WHW)(CLW) (D.N.J.) (Mylan Pharmaceuticals and Mylan Inc.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 78 of the Complaint and therefore denies them.

79. Mylan Inc. and Mylan Pharmaceuticals have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g.*, *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*, Civil Action No. 14-2094 (ES)(MAH) (D.N.J.); *Mylan Inc., et al. v. Apotex Inc., et al.*, Civil Action No. 14-4560 (MAS)(LHG) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 79 of the Complaint and therefore denies them.

Personal Jurisdiction: Breckenridge

80. This Court has personal jurisdiction over Breckenridge by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Breckenridge is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100973602. Breckenridge is also registered with the State of New Jersey as a drug wholesaler under Registration No. 5002974. On information and belief, Breckenridge purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Breckenridge.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 80 of the Complaint and therefore denies them.

81. On information and belief, Breckenridge is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the

generic drug product described in Breckenridge's ANDA. On information and belief, Breckenridge also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 81 of the Complaint and therefore denies them.

82. This Court has personal jurisdiction over Breckenridge because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Breckenridge intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 82 of the Complaint and therefore denies them.

83. According to Breckenridge's website, Breckenridge maintains an office in Fairfield, NJ for sales and marketing. *See* http://www.bpirx.com/html/index.aspx?p32sda=locations&psdge87d=290&tl97abi=86.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 83 of the Complaint and therefore denies them.

84. On information and belief, Breckenridge has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Otsuka Pharm. Co., Ltd. v. Standard Chem. & Pharm. Co., Ltd., et al.*, Civil Action No. 15-6353 (JBS)(KMW) (D.N.J.); *Sanofi-Aventis U.S. LLC, et al. v. Breckenridge Pharmaceutical, Inc.*, Civil Action No. 15-1836 (MAS)(LHG) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 84 of the Complaint and therefore denies them.

85. Breckenridge has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g.*, *Breckenridge Pharmaceutical, Inc. v. Sonar Products, Inc.*, Civil Action No. 10-3921 (WHW)(MCA) (D.N.J.).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 85 of the Complaint and therefore denies them.

Acts Giving Rise To This Suit

86. Pursuant to Section 505 of the FFDCA, Hetero filed Hetero's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Hetero's Proposed Products"), before the patents-in-suit expire.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent Hetero is required to answer, Hetero admits that it submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use, and sale of pomalidomide capsules, 1 mg, 2 mg, 3 mg, and 4 mg, as soon as legally permissible, and that its ANDA satisfied all applicable legal, statutory, and regulatory requirements for filing. Hetero denies all remaining allegations of paragraph 86.

87. On information and belief, following FDA approval of Hetero's ANDA, Defendants Hetero Labs, Hetero Unit-V, Hetero Drugs, and Hetero USA will work in concert with one another to make, use, sell, or offer to sell Hetero's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 87.

88. On information and belief, in connection with the filing of its ANDA as described above, Hetero provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hetero's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

ANSWER: Admitted.

89. No earlier than March 29, 2017, Hetero sent written notice of its Paragraph IV Certification to Celgene ("Hetero's Notice Letter"). Hetero's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's Notice Letter also informed Celgene that Hetero seeks approval to market Hetero's Proposed Products before the patents-in-suit expire. Hetero specifically directed Hetero's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero admits to sending Hetero's Notice Letter dated March 29, 2017, to Celegne Corporation in Summit, New Jersey, and to its counsel, alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Hetero's ANDA and seeking approval to engage in the commercial manufacture, use, and sale of the product described therein as soon as legally permissible, and that Hetero's Notice Letter complied with all legal, statutory, and regulatory requirements. All other allegations of paragraph 89 are denied.

90. Pursuant to Section 505 of the FFDCA, Aurobindo filed Aurobindo's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Aurobindo's Proposed Products"), before the patents-in-suit expire.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 90 of the Complaint and therefore denies them.

91. On information and belief, following FDA approval of Aurobindo's ANDA, Defendants Aurobindo Ltd., Aurobindo USA, Aurolife, and Eugia will work in concert with one another to make, use, sell, or offer to sell Aurobindo's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 91 of the Complaint and therefore denies them.

92. On information and belief, in connection with the filing of its ANDA as described above, Aurobindo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Aurobindo's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Aurobindo's ANDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 92 of the Complaint and therefore denies them.

93. No earlier than April 5, 2017, Aurobindo sent written notice of its Paragraph IV Certification to Celgene ("Aurobindo's Notice Letter"). Aurobindo's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA. Aurobindo's Notice Letter also informed Celgene that Aurobindo seeks approval to market Aurobindo's Proposed Products before the patents-in-suit expire. Aurobindo specifically directed Aurobindo's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 93 of the Complaint and therefore denies them.

94. Pursuant to Section 505 of the FFDCA, Apotex filed Apotex's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Apotex's Proposed Products"), before the patents-in-suit expire.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 94 of the Complaint and therefore denies them.

95. On information and belief, following FDA approval of Apotex's ANDA, Defendants Apotex Inc. and Apotex Corp. will work in concert with one another to make, use, sell, or offer to sell Apotex's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 95 of the Complaint and therefore denies them.

96. On information and belief, in connection with the filing of its ANDA as described above, Apotex provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Apotex's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Apotex's ANDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 96 of the Complaint and therefore denies them.

97. No earlier than March 30, 2017, Apotex sent written notice of its Paragraph IV Certification to Celgene ("Apotex's Notice Letter"). Apotex's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Apotex's ANDA. Apotex's Notice Letter also informed Celgene that Apotex seeks approval to market Apotex's Proposed Products before the patents-in-suit expire. Apotex specifically directed Apotex's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 97 of the Complaint and therefore denies them.

98. Pursuant to Section 505 of the FFDCA, Mylan filed Mylan's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Mylan's Proposed Products"), before the patents-in-suit expire.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 98 of the Complaint and therefore denies them.

99. On information and belief, following FDA approval of Mylan's ANDA, Defendants Mylan Pharmaceuticals, Mylan N.V., and Mylan Inc. will work in concert with one another to make, use, sell, or offer to sell Mylan's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 99 of the Complaint and therefore denies them.

100. On information and belief, in connection with the filing of its ANDA as described above, Mylan provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Mylan's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Mylan's ANDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 100 of the Complaint and therefore denies them.

101. No earlier than April 6, 2017, Mylan sent written notice of its Paragraph IV Certification to Celgene ("Mylan's Notice Letter"). Mylan's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Mylan's ANDA. Mylan's Notice Letter also informed Celgene that Mylan seeks approval to market Mylan's Proposed Products before the patents-in-suit expire. Mylan specifically directed Mylan's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 101 of the Complaint and therefore denies them.

102. Pursuant to Section 505 of the FFDCA, Breckenridge filed Breckenridge's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg ("Breckenridge's Proposed Products"), before the patents-in-suit expire.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 102 of the Complaint and therefore denies them.

103. On information and belief, following FDA approval of Breckenridge's ANDA, Defendant Breckenridge will make, use, sell, or offer to sell Breckenridge's Proposed Products throughout the United States, or import such generic products into the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 103 of the Complaint and therefore denies them.

104. On information and belief, in connection with the filing of its ANDA as described above, Breckenridge provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Breckenridge's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Breckenridge's ANDA.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 104 of the Complaint and therefore denies them.

105. No earlier than April 11, 2017, Breckenridge sent written notice of its Paragraph IV Certification to Celgene ("Breckenridge's Notice Letter"). Breckenridge's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Breckenridge's ANDA. Breckenridge's Notice Letter also informed Celgene that Breckenridge seeks approval to market Breckenridge's Proposed Products before the patents-in-suit expire. Breckenridge specifically directed Breckenridge's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 105 of the Complaint and therefore denies them.

Count I: Infringement of the '262 Patent by Hetero

106. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-105 as if fully set forth herein.

107. Hetero's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

108. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '262 patent.

ANSWER: Admitted.

109. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 109. Hetero also denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

110. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 110 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 110. Hetero also denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

111. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 111. Hetero also denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

112. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '262 patent is not enjoined.

ANSWER: Denied.

113. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

114. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied

Count II: Infringement of the '262 Patent by Aurobindo

115. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-114 as if fully set forth herein.

116. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 116 of the Complaint and therefore denies them.

117. There is a justiciable controversy between Celgene and Aurobindo as to the infringement of the '262 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 117 of the Complaint and therefore denies them.

118. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 118 of the Complaint and therefore denies them.

119. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 119 of the Complaint and therefore denies them.

120. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Aurobindo's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 120 of the Complaint and therefore denies them.

121. Celgene will be substantially and irreparably damaged and harmed if Aurobindo's infringement of the '262 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 121 of the Complaint and therefore denies them.

122. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 122 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 122 of the Complaint and therefore denies them. To the extent the allegations of paragraph 122 are directed at Hetero, denied.

123. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 123 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 123 of the Complaint and therefore denies them. To the extent the allegations of paragraph 123 are directed at Hetero, denied.

Count III: Infringement of the '262 Patent by Apotex

124. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-123 as if fully set forth herein.

125. Apotex's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 125 of the Complaint and therefore denies them.

126. There is a justiciable controversy between Celgene and Apotex as to the infringement of the '262 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 126 of the Complaint and therefore denies them.

127. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 127 of the Complaint and therefore denies them.

128. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's

ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 128 of the Complaint and therefore denies them.

129. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 129 of the Complaint and therefore denies them.

130. Celgene will be substantially and irreparably damaged and harmed if Apotex's infringement of the '262 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 130 of the Complaint and therefore denies them.

131. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 131 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 131 of the Complaint and therefore denies them. To the extent the allegations of paragraph 131 are directed at Hetero, denied.

132. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 132 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 132 of the Complaint and therefore denies them. To the extent the allegations of paragraph 132 are directed at Hetero, denied.

Count IV: Infringement of the '262 Patent by Mylan

133. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-132 as if fully set forth herein.

134. Mylan's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 134 of the Complaint and therefore denies them.

135. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '262 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 135 of the Complaint and therefore denies them.

136. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 136 of the Complaint and therefore denies them.

137. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 137 of the Complaint and therefore denies them.

138. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 138 of the Complaint and therefore denies them.

139. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '262 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 139 of the Complaint and therefore denies them.

140. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 140 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 140 of the Complaint and therefore denies them. To the extent the allegations of paragraph 140 are directed at Hetero, denied.

141. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 141 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 141 of the Complaint and therefore denies them. To the extent the allegations of paragraph 141 are directed at Hetero, denied.

Count V: Infringement of the '262 Patent by Breckenridge

142. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-141 as if fully set forth herein.

143. Breckenridge's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Breckenridge's Proposed Products, prior to the expiration of the '262 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 143 of the Complaint and therefore denies them.

144. There is a justiciable controversy between Celgene and Breckenridge as to the infringement of the '262 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 144 of the Complaint and therefore denies them.

145. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will infringe one or more claims of the '262 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 145 of the Complaint and therefore denies them.

146. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will induce infringement of one or more claims of the '262 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, upon FDA approval of Breckenridge's ANDA, Breckenridge will intentionally encourage acts of direct infringement with knowledge of the '262 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 146 of the Complaint and therefore denies them.

147. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will contributorily infringe one or more claims of the '262 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, Breckenridge has had and continues to have knowledge that Breckenridge's Proposed Products are especially adapted for a use that infringes one or more claims of the '262 patent and that there is no substantial non-infringing use for Breckenridge's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 147 of the Complaint and therefore denies them.

148. Celgene will be substantially and irreparably damaged and harmed if Breckenridge's infringement of the '262 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 148 of the Complaint and therefore denies them.

149. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 149 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 149 of the Complaint and therefore denies them. To the extent the allegations of paragraph 149 are directed at Hetero, denied.

150. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 150 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 150 of the Complaint and therefore denies them. To the extent the allegations of paragraph 150 are directed at Hetero, denied.

Count VI: Infringement of the '939 Patent by Hetero

151. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-150 as if fully set forth herein.

152. Hetero's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 152 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

153. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '939 patent.

ANSWER: Admitted.

154. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 154 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 154. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

155. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '939 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 155 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 155. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

156. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '939 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 156 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 156. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

157. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '939 patent is not enjoined.

ANSWER: Denied.

158. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

159. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count VII: Infringement of the '939 Patent by Aurobindo

160. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-159 as if fully set forth herein.

161. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 161 of the Complaint and therefore denies them.

162. There is a justiciable controversy between Celgene and Aurobindo as to the infringement of the '939 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 162 of the Complaint and therefore denies them.

163. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 163 of the Complaint and therefore denies them.

164. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '939 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 164 of the Complaint and therefore denies them.

165. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Proposed Products are especially adapted for a use that infringes one or more claims of the '939 patent and that there is no substantial non-infringing use for Aurobindo's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 165 of the Complaint and therefore denies them.

166. Celgene will be substantially and irreparably damaged and harmed if Aurobindo's infringement of the '939 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 166 of the Complaint and therefore denies them.

167. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 167 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 167 of the Complaint and therefore denies them. To the extent the allegations of paragraph 167 are directed at Hetero, denied.

168. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 168 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 168 of the Complaint and therefore denies them. To the extent the allegations of paragraph 168 are directed at Hetero, denied.

Count VIII: Infringement of the '939 Patent by Apotex

169. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-168 as if fully set forth herein.

170. Apotex's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 170 of the Complaint and therefore denies them.

171. There is a justiciable controversy between Celgene and Apotex as to the infringement of the '939 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 171 of the Complaint and therefore denies them.

172. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 172 of the Complaint and therefore denies them.

173. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '939 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 173 of the Complaint and therefore denies them.

174. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that

infringes one or more claims of the '939 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 174 of the Complaint and therefore denies them.

175. Celgene will be substantially and irreparably damaged and harmed if Apotex's infringement of the '939 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 175 of the Complaint and therefore denies them.

176. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 176 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 176 of the Complaint and therefore denies them. To the extent the allegations of paragraph 176 are directed at Hetero, denied.

177. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 177 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 177 of the Complaint and therefore denies them. To the extent the allegations of paragraph 177 are directed at Hetero, denied.

Count IX: Infringement of the '939 Patent by Mylan

178. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-177 as if fully set forth herein.

179. Mylan's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 179 of the Complaint and therefore denies them.

180. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '939 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 180 of the Complaint and therefore denies them.

181. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 181 of the Complaint and therefore denies them.

182. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '939 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 182 of the Complaint and therefore denies them.

183. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '939 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 183 of the Complaint and therefore denies them.

184. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '939 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 184 of the Complaint and therefore denies them.

185. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 185 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 185 of the Complaint and therefore denies them. To the extent the allegations of paragraph 185 are directed at Hetero, denied.

186. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 186 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 186 of the Complaint and therefore denies them. To the extent the allegations of paragraph 186 are directed at Hetero, denied.

Count X: Infringement of the '939 Patent by Breckenridge

187. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-186 as if fully set forth herein.

188. Breckenridge's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Breckenridge's Proposed Products, prior to the expiration of the '939 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 188 of the Complaint and therefore denies them.

189. There is a justiciable controversy between Celgene and Breckenridge as to the infringement of the '939 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 189 of the Complaint and therefore denies them.

190. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will infringe one or more claims of the '939 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 190 of the Complaint and therefore denies them.

191. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will induce infringement of one or more claims of the '939 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, upon FDA approval of Breckenridge's ANDA, Breckenridge will intentionally encourage acts of direct infringement with knowledge of the '939 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 191 of the Complaint and therefore denies them.

192. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will contributorily infringe one or more claims of the '939 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, Breckenridge has had and continues to have knowledge that Breckenridge's Proposed Products are especially adapted for a use that infringes one or more claims of the '939 patent and that there is no substantial non-infringing use for Breckenridge's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 192 of the Complaint and therefore denies them.

193. Celgene will be substantially and irreparably damaged and harmed if Breckenridge's infringement of the '939 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 193 of the Complaint and therefore denies them.

194. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 194 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 194 of the Complaint and therefore denies them. To the extent the allegations of paragraph 194 are directed at Hetero, denied.

195. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 195 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 195 of the Complaint and therefore denies them. To the extent the allegations of paragraph 195 are directed at Hetero, denied.

Count XI: Infringement of the '428 Patent by Hetero

196. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-195 as if fully set forth herein.

197. Hetero's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 197 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 197.

198. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '428 patent.

ANSWER: Admitted.

199. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 199 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 199. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

200. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 200 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 200. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

201. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '428 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 201 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 201. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

202. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '428 patent is not enjoined.

ANSWER: Denied.

203. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

204. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count XII: Infringement of the '428 Patent by Aurobindo

205. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-204 as if fully set forth herein.

206. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed Products, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 206 of the Complaint and therefore denies them.

207. There is a justiciable controversy between Celgene and Aurobindo as to the infringement of the '428 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 207 of the Complaint and therefore denies them.

208. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 208 of the Complaint and therefore denies them.

209. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 209 of the Complaint and therefore denies them.

210. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Proposed Products are especially adapted for a use that infringes one or more claims of the '428 patent and that there is no substantial non-infringing use for Aurobindo's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 210 of the Complaint and therefore denies them.

211. Celgene will be substantially and irreparably damaged and harmed if Aurobindo's infringement of the '428 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 211 of the Complaint and therefore denies them.

212. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 212 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 212 of the Complaint and therefore denies them. To the extent the allegations of paragraph 212 are directed at Hetero, denied.

213. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 213 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 213 of the Complaint and therefore denies them. To the extent the allegations of paragraph 213 are directed at Hetero, denied.

Count XIII: Infringement of the '428 Patent by Apotex

214. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-213 as if fully set forth herein.

215. Apotex's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's Proposed Products, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 215 of the Complaint and therefore denies them.

216. There is a justiciable controversy between Celgene and Apotex as to the infringement of the '428 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 216 of the Complaint and therefore denies them.

217. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 217 of the Complaint and therefore denies them.

218. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 218 of the Complaint and therefore denies them.

219. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '428 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 219 of the Complaint and therefore denies them.

220. Celgene will be substantially and irreparably damaged and harmed if Apotex's infringement of the '428 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 220 of the Complaint and therefore denies them.

221. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 221 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 221 of the Complaint and therefore denies them. To the extent the allegations of paragraph 221 are directed at Hetero, denied.

222. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 222 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 222 of the Complaint and therefore denies them. To the extent the allegations of paragraph 222 are directed at Hetero, denied.

Count XIV: Infringement of the '428 Patent by Mylan

223. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-222 as if fully set forth herein.

224. Mylan's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 224 of the Complaint and therefore denies them.

225. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '428 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 225 of the Complaint and therefore denies them.

226. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 226 of the Complaint and therefore denies them.

227. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 227 of the Complaint and therefore denies them.

228. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more

claims of the '428 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 228 of the Complaint and therefore denies them.

229. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '428 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 229 of the Complaint and therefore denies them.

230. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 230 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 230 of the Complaint and therefore denies them. To the extent the allegations of paragraph 230 are directed at Hetero, denied.

231. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 231 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 231 of the Complaint and therefore denies them. To the extent the allegations of paragraph 231 are directed at Hetero, denied.

Count XV: Infringement of the '428 Patent by Breckenridge

232. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-231 as if fully set forth herein.

233. Breckenridge's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Breckenridge's Proposed Products, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 233 of the Complaint and therefore denies them.

234. There is a justiciable controversy between Celgene and Breckenridge as to the infringement of the '428 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 234 of the Complaint and therefore denies them.

235. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 235 of the Complaint and therefore denies them.

236. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, upon FDA approval of Breckenridge's ANDA, Breckenridge will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 236 of the Complaint and therefore denies them.

237. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, Breckenridge has had and continues to have knowledge that Breckenridge's Proposed Products are especially adapted for a use that infringes one or more claims of the '428 patent and that there is no substantial non-infringing use for Breckenridge's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 237 of the Complaint and therefore denies them.

238. Celgene will be substantially and irreparably damaged and harmed if Breckenridge's infringement of the '428 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 238 of the Complaint and therefore denies them.

239. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 239 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 239 of the Complaint and therefore denies them. To the extent the allegations of paragraph 239 are directed at Hetero, denied.

240. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 240 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 240 of the Complaint and therefore denies them. To the extent the allegations of paragraph 240 are directed at Hetero, denied.

Count XVI: Infringement of the '427 Patent by Hetero

241. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-240 as if fully set forth herein.

242. Hetero's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's Proposed Products, prior to the expiration of the '427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 242 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 242.

243. There is a justiciable controversy between Celgene and Hetero as to the infringement of the '427 patent.

ANSWER: Admitted.

244. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States.

ANSWER: Paragraph 244 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 244. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(a).

245. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '427 patent under 35 U.S.C. § 271(b)

by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '427 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 245 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 245. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(b).

246. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Hetero's Proposed Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's Proposed Products are especially adapted for a use that infringes one or more claims of the '427 patent and that there is no substantial non-infringing use for Hetero's Proposed Products.

ANSWER: Paragraph 246 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of paragraph 246. Hetero further denies that subject matter jurisdiction exists for any claim under 35 U.S.C. § 271(c).

247. Celgene will be substantially and irreparably damaged and harmed if Hetero's infringement of the '427 patent is not enjoined.

ANSWER: Denied.

248. Celgene does not have an adequate remedy at law.

ANSWER: Denied.

249. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count XVII: Infringement of the '427 Patent by Aurobindo

250. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-249 as if fully set forth herein.

251. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed Products, prior to the expiration of the '427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 251 of the Complaint and therefore denies them.

252. There is a justiciable controversy between Celgene and Aurobindo as to the infringement of the '427 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 252 of the Complaint and therefore denies them.

253. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 253 of the Complaint and therefore denies them.

254. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '427 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '427 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 254 of the Complaint and therefore denies them.

255. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Products in the United States. On information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Proposed Products are especially adapted for a use that infringes one or more claims of the '427 patent and that there is no substantial non-infringing use for Aurobindo's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 255 of the Complaint and therefore denies them.

256. Celgene will be substantially and irreparably damaged and harmed if Aurobindo's infringement of the '427 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 256 of the Complaint and therefore denies them.

257. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 257 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 257 of the Complaint and therefore denies them. To the extent the allegations of paragraph 257 are directed at Hetero, denied.

258. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 258 are directed at Aurobindo, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 258 of the Complaint and therefore denies them. To the extent the allegations of paragraph 258 are directed at Hetero, denied.

Count XVIII: Infringement of the '427 Patent by Apotex

259. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-258 as if fully set forth herein.

260. Apotex's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's Proposed Products, prior to the expiration of the '427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 260 of the Complaint and therefore denies them.

261. There is a justiciable controversy between Celgene and Apotex as to the infringement of the '427 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 261 of the Complaint and therefore denies them.

262. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 262 of the Complaint and therefore denies them.

263. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '427 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '427 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 263 of the Complaint and therefore denies them.

264. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Apotex's Proposed Products in the United States. On information and belief, Apotex has had and continues to have knowledge that Apotex's Proposed Products are especially adapted for a use that infringes one or more claims of the '427 patent and that there is no substantial non-infringing use for Apotex's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 264 of the Complaint and therefore denies them.

265. Celgene will be substantially and irreparably damaged and harmed if Apotex's infringement of the '427 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 265 of the Complaint and therefore denies them.

266. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 266 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 266 of the Complaint and therefore denies them. To the extent the allegations of paragraph 266 are directed at Hetero, denied.

267. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 267 are directed at Apotex, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 267 of the Complaint and therefore denies them. To the extent the allegations of paragraph 267 are directed at Hetero, denied.

Count XIX: Infringement of the '427 Patent by Mylan

268. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-267 as if fully set forth herein.

269. Mylan's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 269 of the Complaint and therefore denies them.

270. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '427 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 270 of the Complaint and therefore denies them.

271. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 271 of the Complaint and therefore denies them.

272. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '427 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '427 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 272 of the Complaint and therefore denies them.

273. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '427 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 273 of the Complaint and therefore denies them.

274. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '427 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 274 of the Complaint and therefore denies them.

275. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 275 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 275 of the Complaint and therefore denies them. To the extent the allegations of paragraph 275 are directed at Hetero, denied.

276. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 276 are directed at Mylan, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 276 of the Complaint and therefore denies them. To the extent the allegations of paragraph 276 are directed at Hetero, denied.

Count XX: Infringement of the '427 Patent by Breckenridge

277. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to paragraphs 1-276 as if fully set forth herein.

278. Breckenridge's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Breckenridge's Proposed Products, prior to the expiration of the '427 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 278 of the Complaint and therefore denies them.

279. There is a justiciable controversy between Celgene and Breckenridge as to the infringement of the '427 patent.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 279 of the Complaint and therefore denies them.

280. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will infringe one or more claims of the '427 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 280 of the Complaint and therefore denies them.

281. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will induce infringement of one or more claims of the '427 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, upon FDA approval of Breckenridge's ANDA, Breckenridge will intentionally encourage acts of direct infringement with knowledge of the '427 patent and knowledge that its acts are encouraging infringement.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 281 of the Complaint and therefore denies them.

282. Unless enjoined by this Court, upon FDA approval of Breckenridge's ANDA, Breckenridge will contributorily infringe one or more claims of the '427 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, Breckenridge has had and

continues to have knowledge that Breckenridge's Proposed Products are especially adapted for a use that infringes one or more claims of the '427 patent and that there is no substantial non-infringing use for Breckenridge's Proposed Products.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 282 of the Complaint and therefore denies them.

283. Celgene will be substantially and irreparably damaged and harmed if Breckenridge's infringement of the '427 patent is not enjoined.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 283 of the Complaint and therefore denies them.

284. Celgene does not have an adequate remedy at law.

ANSWER: To the extent the allegations of paragraph 284 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 284 of the Complaint and therefore denies them. To the extent the allegations of paragraph 284 are directed at Hetero, denied.

285. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: To the extent the allegations of paragraph 285 are directed at Breckenridge, Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of paragraph 285 of the Complaint and therefore denies them. To the extent the allegations of paragraph 285 are directed at Hetero, denied.

PRAYER FOR RELIEF AGAINST HETERO

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Hetero has infringed the patents-in-suit by submitting ANDA No. 210236;

(B) A Judgment that Hetero has infringed, and that Hetero's making, using, selling, offering to sell, or importing Hetero's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210236 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Hetero and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Hetero's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Hetero, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Hetero's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Hetero has committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Hetero engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Hetero's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

ANSWER: Hetero denies all allegations not expressly admitted herein. Hetero further denies that Plaintiff is entitled to any of the relief requested, and requests that the Complaint be dismissed with prejudice and that Hetero be awarded its fees and costs under 35 U.S.C. § 285 for defending this suit.

PRAYER FOR RELIEF AGAINST AUROBINDO

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Aurobindo has infringed the patents-in-suit by submitting ANDA No. 210249;

(B) A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, selling, offering to sell, or importing Aurobindo's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210249 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Aurobindo's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Aurobindo, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Aurobindo's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Aurobindo has committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Aurobindo engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Aurobindo's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the Prayer for Relief Against Aurobindo and therefore denies that Plaintiff is entitled to the requested relief.

PRAYER FOR RELIEF AGAINST APOTEX

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Apotex has infringed the patents-in-suit by submitting ANDA No. 210164;

(B) A Judgment that Apotex has infringed, and that Apotex's making, using, selling, offering to sell, or importing Apotex's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210164 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Apotex's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Apotex, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit,

until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Apotex has committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Apotex engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the Prayer for Relief Against Apotex and therefore denies that Plaintiff is entitled to the requested relief.

PRAYER FOR RELIEF AGAINST MYLAN

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

A. A Judgment that Mylan has infringed the patents-in-suit by submitting ANDA No. 210275;

B. A Judgment that Mylan has infringed, and that Mylan's making, using, selling, offering to sell, or importing Mylan's Proposed Products will infringe one or more claims of the patents-in-suit;

C. An Order that the effective date of FDA approval of ANDA No. 210275 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

D. Preliminary and permanent injunctions enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Mylan's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

F. A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Mylan's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

G. To the extent that Mylan has committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

H. If Mylan engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Mylan's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

I. A Judgment declaring that the patents-in-suit remain valid and enforceable;

J. A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

K. A Judgment awarding Celgene its costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the Prayer for Relief Against Mylan and therefore denies that Plaintiff is entitled to the requested relief.

PRAYER FOR RELIEF AGAINST BRECKENRIDGE

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

A. A Judgment that Breckenridge has infringed the patents-in-suit by submitting ANDA No. 210111;

B. A Judgment that Breckenridge has infringed, and that Breckenridge's making, using, selling, offering to sell, or importing Breckenridge's Proposed Products will infringe one or more claims of the patents-in-suit;

C. An Order that the effective date of FDA approval of ANDA No. 210111 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

D. Preliminary and permanent injunctions enjoining Breckenridge and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Breckenridge's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Breckenridge, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

F. A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Breckenridge's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

G. To the extent that Breckenridge has committed any acts with respect to the methods of use and administration of pomalidomide, or pharmaceutical compositions containing pomalidomide, claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

H. If Breckenridge engages in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Breckenridge's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

I. A Judgment declaring that the patents-in-suit remain valid and enforceable;

J. A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

K. A Judgment awarding Celgene its costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the Prayer for Relief Against Breckenridge and therefore denies that Plaintiff is entitled to the requested relief.

HETERO'S SEPARATE DEFENSES

Without prejudice to the denials set forth in its **ANSWER**, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Hetero avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '262 PATENT)

The claims of the '262 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '262 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '262 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '262 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '262 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '939 PATENT)

The claims of the '939 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '939 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '939 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '939 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '939 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '428 PATENT)

The claims of the '428 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '428 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '428 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '428 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '428 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '427 PATENT)

The claims of the '427 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '427 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '427 Patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '427 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 210236 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '427 Patent.

THIRTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FOURTEENTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

FIFTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Hetero reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Hetero Labs Limited, Hetero Labs Limited – Unit V, and Hetero USA, Inc. (collectively, "Hetero"), by way of its attorneys, hereby states for its Counterclaims against Celgene Corporation ("Celgene") Plaintiff/Counterclaim-Defendant. ("Plaintiff/Counterclaim-Defendant"), the following:

1. Hetero repeats and incorporates by reference each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint.

THE PARTIES

2. Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Andhra Pradesh, India.

3. Hetero Labs Limited Unit-V is a division of Hetero Labs Limited and is located at Polepally, Jadcherla, Mahabubnagar – 509 301, Andhra Pradesh, India.

4. Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

5. Upon information and belief, Plaintiff/Counter-Defendant Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, and 28 U.S.C. §§ 2201 and 2202, and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Hetero and Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

9. This court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiff/Counterclaim-Defendant is doing business in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

I. FDA Approval of Brand Name Drugs – New Drug Applications ("NDAs")

11. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman Act" or "Hatch-Waxman "), and as further amended by the MMA, sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

12. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

13. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

14. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

II. Generic Competition – Abbreviated New Drug Applications ("ANDAs")

15. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs with the purpose of decreasing the price of pharmaceuticals through increased

competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

16. To receive approval of its ANDA, an applicant must, inter alia, show that its generic drug is "bioequivalent" to the Reference Listed Drug, the Orange Book listed drug identified as the drug product upon which the ANDA applicant relies upon in seeking approval of its ANDA. *See* 21 U.S.C. § 355(j)(4)(F); 21 C.F.R. 314.3(b).

17. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

18. With certain exceptions not applicable here, when seeking FDA approval to market prior to patent expiration, an ANDA applicant can submit a so-called "Paragraph IV certification" asserting that, in the applicant's opinion and to the best of its knowledge, the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

19. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA-holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

20. If the patent owner brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), the FDA cannot approve the ANDA for 30 months, unless the district court enters an order shortening that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Thus, patent owners have a significant financial incentive to file suit regardless of merit (or lack thereof).

21. If the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. If the patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, Congress explicitly mandated in the MMA amendments to the FFDCA and Hatch-Waxman that an ANDA applicant is entitled to bring and maintain a declaratory judgment action when it is not sued. *See* 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5).

23. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA if the applicant asserts non-infringement. *See* 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

24. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II); *see also* 35 U.S.C. § 271(e)(5).

25. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to the Application is accepted.

26. The declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes the ANDA at issue in these proceedings.

FACTS COMMON TO ALL COUNTS

27. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent Nos.: 8,198,262 ("the '262 patent), 8,673,939 ("the '939 patent"), 8,735,428 ("the '428 patent"), 8,828,427 ("the '427 patent"), 6,315,720 ("the '720 patent"), 6,561,977 ("the '977 patent"), 6,755,784 ("the '784 patent"), 8,315,886 ("the '886 patent"), and 8,626,531 ("the '531 patent"), (collectively, "the Patents-in-Suit.)

28. Upon information and belief, true and correct copies of the '262, '939, '428, and '427 patents are attached to Plaintiff/Counter-Defendant's Complaint as Exhibits A-D, respectively. Upon information and belief, true and correct copies of the '720, '977, '784, '886, and '531 patents are attached hereto as Exhibits A through E, respectively.

29. On or about June 12, 2012, the U.S. Patent & Trademark Office ("PTO") issued the '262 patent.

30. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the '262 patent and has the right to enforce the '262 patent.

31. On or about March 18, 2014, the PTO issued the '939 patent.

32. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the '939 patent and has the right to enforce the '939 patent.

33. On or about May 27, 2014, the PTO issued the ‘428 patent.

34. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘428 patent and has the right to enforce the ‘428 patent.

35. On or about September 9, 2014, the PTO issued the ‘427 patent.

36. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘427 patent and has the right to enforce the ‘427 patent.

37. On or about November 13, 2001, the PTO issued the ‘720 patent.

38. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘720 patent and has the right to enforce the ‘720 patent.

39. On or about May 13, 2003, the PTO issued the ‘977 patent.

40. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘977 patent and has the right to enforce the ‘977 patent.

41. On or about June 29, 2004, the PTO issued the ‘784 patent.

42. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘784 patent and has the right to enforce the ‘784 patent.

43. On or about November 20, 2012, the PTO issued the ‘886 patent.

44. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘886 patent and has the right to enforce the ‘886 patent.

45. On or about January 7, 2014, the PTO issued the ‘531 patent.

46. On information and belief, Plaintiff/Counterclaim-Defendant is the owner of the ‘531 patent and has the right to enforce the ‘531 patent.

47. Plaintiff/Counterclaim-Defendant purports to be the holder of approved New Drug Application ("NDA") No. 204026 for pomalidomide capsules, which is sold in the United States under the trademark POMALYST®.

48. Plaintiff/Counterclaim-Defendant listed the Patents-in-Suit in the FDA's Orange Book for POMALYST®, and continues to maintain such listings. As a consequence of listing the Patents-in-Suit in the Orange Book, Plaintiff is representing to the world that the Patents-in-Suit cover POMALYST® and pomalidomide, and that Patents-in-Suit could reasonably be asserted against anyone who files an ANDA referencing POMALYST®, including such ANDAs containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") to one or more of the Patents-in-Suit.

49. Hetero filed ANDA No. 210236 with FDA seeking approval for Hetero's proposed pomalidomide capsules products described therein ("Hetero ANDA Products"), identifying NDA No. 204026 as the reference listed drug.

50. Hetero's ANDA seeks FDA approval to market the Hetero ANDA Products described within ANDA No. 210236 before the expiration of the Patents-in-Suit listed in the Orange Book, and Hetero's ANDA includes and maintains a Paragraph IV Certification as to each of the Patents-in-Suit. By letter dated March 29, 2017, Hetero notified Plaintiff/Counterclaim-Defendant of Hetero's Paragraph IV Certification as to each of the Patents-in-Suit, detailing the legal and factual bases as to why the Patents-in-Suit are invalid and/or not infringed by the products described in Hetero's ANDA No. 210236 ("the Notice Letter").

51. In response to the Notice Letter, Plaintiff/Counterclaim-Defendant sued Hetero in this District for alleged infringement of the '262 patent, the '939 patent, the '428 patent, and the

'427 patent, but not the '720 patent, the '977 patent, the '784 patent, the '886 patent, and the '531 patent. Celgene's suit triggered a statutory stay of FDA approval of Hetero's ANDA No. 210236.

52. Despite the Notice Letter, Plaintiff/Counterclaim-Defendant maintains the listing of the Patents-in-Suit in the Orange Book for POMALYST®, thereby continuing to cause injury to Hetero.

COUNT I

Declaratory Judgment of Invalidity of the '262 Patent

53. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-52 as though fully set forth herein.

54. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '262 patent.

55. The claims of the '262 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

56. The claims of the '262 patent are obvious under 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '262 patent was disclosed in the prior art before the earliest possible priority date of the '262 patent, including, but not limited to, those references disclosed in the Notice Letter. A person of ordinary skill in the art would have been motivated to combine those references as of the earliest possible priority date of the '262 patent, and would have had a reasonable expectation of success in doing so. As to the '262 patent, invalidating prior art references include at least: (a) S. Lentzsch et al., *S-3-Amino-phthalimido-glutarimide inhibits angiogenesis and growth of B-cell*

nopasias in mice, 62 Cancer Research 2300 (April 15, 2002) ("the Lentzsch reference"); (b) Hideshima, et al., *Thalidomide and its Analogs Overcome Resistance of Human Multiple Myeloma Cells to Conventional Therapy,* 96 Blood 2943 (Nov. 1, 2000) ("the Hideshima reference"); (c) R.J. D'Amato, et al., *Mechanism of Action of Thalidomide and 3-Aminothalidomide in Multiple Myeloma,* 28 Seminars in Oncology 597 (Dec. 2001) ("the D'Amato reference"); (d) U.S. Patent No. 6,316,471 entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" issued on November 13, 2001 ("the '471 patent"); and (e) U.S. Patent No. 5,635,517, entitled "Method of Reducing TNFα Levels with Amino Substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo- and 1,3-dioxoisoindolines" issued on June 3, 1997 ("the '517 patent").

57. There is no objective evidence of non-obviousness of the claims of the '262 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '262 patent.

58. The claims of the '262 patent are also invalid under 35 U.S.C. § 112, for lack of enablement. The '262 patent fails to describe, identify, or teach effective methods of treating multiple myeloma through administration of pomalidomide. The '262 patent does not provide any data, clinical or otherwise, regarding actual administration of pomalidomide to patients. As such, the claims of the '262 patent are invalid because the patent does not enable the full scope of the claims.

59. The claims of the '262 patent are also invalid under 35 U.S.C. § 112 for insufficient written description at least because the specification of the '262 patent does not "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351

(Fed. Cir. 2010). The '262 patent would not convey to a person of skill in the art that the inventor was in possession of the claimed subject matter because the '262 patent is devoid of any data, studies, or other evidence that the inventors had actually invented a method for treating multiple myeloma by administration of pomalidomide. As such, the claims of the '262 patent are invalid for lack of written description.

60. Hetero is entitled to a judicial declaration that the claims of the '262 patent are invalid.

COUNT II

Declaratory Judgment of Non-Infringement of the '262 Patent

61. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-60 as though fully set forth herein.

62. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '262 patent.

63. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '262 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '262 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

64. Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '262 patent, either literally or under the doctrine of equivalents.

COUNT III

Declaratory Judgment of Invalidity of the '939 Patent

65. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-64 as though fully set forth herein.

66. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '939 patent.

67. The claims of the '939 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

68. The claims of the '939 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '939 patent was disclosed in the prior art before the earliest possible priority date of the '939 patent, including, but not limited to, those references disclosed in the Notice Letter. A person of ordinary skill in the art would have been motivated to combine those references as of the earliest possible priority date of the '939 patent, and would have had a reasonable expectation of success in doing so. As to the '939 patent, invalidating prior art references include at least: (a) the Lentzsch reference, (b) the Hideshima reference, (c) the D'Amato reference, (d) the '471 patent, and (3) the '517 patent.

69. There is no objective evidence of non-obviousness of the claims of the '939 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '939 patent.

70. The claims of the '939 patent are also invalid under 35 U.S.C. § 112, for lack of enablement. The '939 patent fails to describe, identify, or teach effective methods of treating multiple myeloma through administration of pomalidomide. The '939 patent does not provide any data, clinical or otherwise, regarding actual administration of pomalidomide to patients. As such, the claims of the '939 patent are invalid because the patent does not enable the full scope of the claims.

71. The claims of the '939 patent are also invalid under 35 U.S.C. § 112 for insufficient written description at least because the specification of the '939 patent does not "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The '939 patent would not convey to a person of skill in the art that the inventor was in possession of the claimed subject matter because the '939 patent is devoid of any data, studies, or other evidence that the inventors had actually invented a method for treating multiple myeloma by administration of pomalidomide. As such, the claims of the '939 patent are invalid for lack of written description.

72. Hetero is entitled to a judicial declaration that the claims of the '939 patent are invalid.

COUNT IV

Declaratory Judgment of Non-Infringement of the '939 Patent

73. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-72 as though fully set forth herein.

74. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '939 patent.

75. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '939 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '939 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

76. Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '939 patent, either literally or under the doctrine of equivalents.

COUNT V

Declaratory Judgment of Invalidity of the '428 Patent

77. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-76 as though fully set forth herein.

78. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '428 patent.

79. The claims of the '428 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

80. The claims of the '428 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '428 patent was disclosed in the prior art before the earliest possible priority date of the '428 patent, including, but not limited to, those references disclosed in the Notice Letter. A person of ordinary skill in the art would have been motivated to combine those references as of the earliest possible priority date of the '428 patent, and would have had a reasonable expectation of success in doing so. As to the '428 patent, invalidating prior art references include at least: (a) the Lentzsch reference, (b) the Hideshima reference, (c) the D'Amato reference, (d) the '471 patent, and (3) the '517 patent.

81. There is no objective evidence of non-obviousness of the claims of the '428 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '428 patent.

82. The claims of the '428 patent are also invalid under 35 U.S.C. § 112, for lack of enablement. The '428 patent fails to describe, identify, or teach effective methods of treating multiple myeloma through administration of pomalidomide. The '428 patent does not provide

any data, clinical or otherwise, regarding actual administration of pomalidomide to patients. As such, the claims of the '428 patent are invalid because the patent does not enable the full scope of the claims.

83. The claims of the '428 patent are also invalid under 35 U.S.C. § 112 for insufficient written description at least because the specification of the '428 patent does not "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The '428 patent would not convey to a person of skill in the art that the inventor was in possession of the claimed subject matter because the '428 patent is devoid of any data, studies, or other evidence that the inventors had actually invented a method for treating multiple myeloma by administration of pomalidomide. As such, the claims of the '428 patent are invalid for lack of written description.

84. Hetero is entitled to a judicial declaration that the claims of the '428 patent are invalid.

COUNT VI

Declaratory Judgment of Non-Infringement of the '428 Patent

85. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-84 as though fully set forth herein.

86. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '428 patent.

87. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and

would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '428 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '428 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

88. Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '428 patent, either literally or under the doctrine of equivalents.

COUNT VII

Declaratory Judgment of Invalidity of the '427 Patent

89. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-88 as though fully set forth herein.

90. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '427 patent.

91. The claims of the '427 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

92. The claims of the '427 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '427 patent was

disclosed in the prior art before the earliest possible priority date of the '427 patent, including, but not limited to, the reference disclosed in the Notice Letter, U.S. Patent Publication No. 20070155791 A1 to Zeldis, which discloses administration of pomalidomide in an amount of 0.5 mg to 5 mg, including through the use of capsules with common pharmaceutically acceptable excipients.

93. There is no objective evidence of non-obviousness of the claims of the '427 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '427 patent.

94. Hetero is entitled to a judicial declaration that the claims of the '427 patent are invalid.

COUNT VIII

Declaratory Judgment of Non-Infringement of the '427 Patent

95. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-94 as though fully set forth herein.

96. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '427 patent.

97. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '427 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '427 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever."

Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

98. Hetero also does not infringe the '427 patent because the patent claims do not cover Hetero's ANDA Product. The claims of the '427 patent all recite exact compositions comprising pomalidomide, which are not found in Hetero's ANDA, as detailed in the Notice Letter to Celgene. By way of a non-limiting example, Hetero's ANDA Product does not comprise pregelatinized starch, sodium stearyl fumarate, or spray dried mannitol in a total capsule weight in the amounts recited in the claims of the '427 patent, either literally or equivalently. For a second, non-limiting example, Hetero's ANDA Product does not comprise "5 mg of 100% pure pomalidomide," as recited in claims 11 and 12 of the '427 patent, either literally or equivalently.

99. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '427 patent, either literally or under the doctrine of equivalents.

COUNT IX

Declaratory Judgment of Invalidity of the '720 Patent

100. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-99 as though fully set forth herein.

101. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '720 patent.

102. The claims of the '720 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

103. The claims of the '720 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '720 patent was disclosed in the prior art before the earliest possible priority date of the '720 patent, including, but not limited to, the references disclosed in the Notice Letter: (a) the Thalomid® Capsules Revised Package Insert published on or around July 15, 1998; (b) U.S. Patent 5,832,449; (c) D.P. Keravich, *Challenges of Thalidomide Distribution in a Hospital Setting,* 56 Am. J. Health-Syst. Pharm. 1721; (d) J.B. Zeldis, *S.T.E.P.S.™ A Comprehensive Program for Controlling and Monitoring Access to Thalidomide,* 21 Clinical Therapeutics 319; (e) J.C. Mundt, *Interactive Voice Response Systems in Clinical Research and Treatmen,* 48 Psychiatric Services 611; (f) R.J. Powell, et al., *Guideline For the Clinical Use and Dispensing of Thalidomide*, 70 Postgrad. Med. J. 901; (g) A.A. Mitchell, et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin,* 333 New. Eng. J. Med. 101; and (h) B.R. Dishman, et al., *Pharmacists' Role in Clozapine Therapy at a Veterans Affairs Medical Center,* 51 Am. J. Hosp. Pharm. 899 (collectively, "the REMS References").

104. There is no objective evidence of non-obviousness of the claims of the '720 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '720 patent.

105. The '720 patent was the subject of *Inter Partes* Review Nos. IPR2015-01096, IPR2015-01102, and IPR2015-01103, each entitled *Coalition for Affordable Drugs VI LLC v. Celgene Corporation*. On October 26, 2016, the U.S. Patent & Trademark Office issued a final

written decision in all three proceedings, holding in each that all claims of the '720 patent are unpatentable. The claims of the '720 patent are thus invalid for the reasons stated in the October 26, 2016 Final Written Decisions in *Inter Partes* Review Nos. IPR2015-01096, IPR2015-01102, and IPR2015-01103.

106. Hetero is entitled to a judicial declaration that the claims of the '720 patent are invalid.

COUNT X

Declaratory Judgment of Non-Infringement of the '720 Patent

107. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-106 as though fully set forth herein.

108. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '720 patent.

109. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '720 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '720 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

110. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '720 patent, either literally or under the doctrine of equivalents.

COUNT XI

Declaratory Judgment of Invalidity of the '977 Patent

111. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-110 as though fully set forth herein.

112. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '977 patent.

113. The claims of the '977 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

114. The claims of the '977 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '977 patent was disclosed in the prior art before the earliest possible priority date of the '977 patent, including, but not limited to, the REMS References disclosed in the Notice Letter.

115. There is no objective evidence of non-obviousness of the claims of the '977 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '977 patent.

116. Hetero is entitled to a judicial declaration that the claims of the '977 patent are invalid.

COUNT XII

Declaratory Judgment of Non-Infringement of the '977 Patent

117. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-116 as though fully set forth herein.

118. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '977 patent.

119. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '977 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '977 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation,* 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

120. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '977 patent, either literally or under the doctrine of equivalents.

COUNT XIII

Declaratory Judgment of Invalidity of the '784 Patent

121. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-120 as though fully set forth herein.

122. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '784 patent.

123. The claims of the '784 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

124. The claims of the '784 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '784 patent was disclosed in the prior art before the earliest possible priority date of the '784 patent, including, but not limited to, the REMS References disclosed in the Notice Letter.

125. There is no objective evidence of non-obviousness of the claims of the '784 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '784 patent.

126. Hetero is entitled to a judicial declaration that the claims of the '784 patent are invalid.

COUNT XIV

Declaratory Judgment of Non-Infringement of the '784 Patent

127. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-126 as though fully set forth herein.

128. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '784 patent.

129. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '784 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '784 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

130. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '784 patent, either literally or under the doctrine of equivalents.

COUNT XV

Declaratory Judgment of Invalidity of the '886 Patent

131. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-130 as though fully set forth herein.

132. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '886 patent.

133. The claims of the '886 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

134. The claims of the '886 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '886 patent was disclosed in the prior art before the earliest possible priority date of the '886 patent, including, but not limited to, the REMS references disclosed in the Notice Letter.

135. There is no objective evidence of non-obviousness of the claims of the '886 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '886 patent.

136. Hetero is entitled to a judicial declaration that the claims of the '886 patent are invalid.

COUNT XVI

Declaratory Judgment of Non-Infringement of the '886 Patent

137. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-136 as though fully set forth herein.

138. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '886 patent.

139. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '886 patent, either literally or under the doctrine of equivalents.

In particular, the claims of the '886 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

140. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '886 patent, either literally or under the doctrine of equivalents.

COUNT XVII

Declaratory Judgment of Invalidity of the '531 Patent

141. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-140 as though fully set forth herein.

142. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '531 patent.

143. The claims of the '531 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

144. The claims of the '531 patent are obvious 35 U.S.C. § 103 to a person of ordinary skill in the art because each and every element of each and every claim of the '531 patent was disclosed in the prior art before the earliest possible priority date of the '531 patent, including, but not limited to, the REMS References disclosed in the Notice Letter.

145. There is no objective evidence of non-obviousness of the claims of the '531 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '531 patent.

146. Hetero is entitled to a judicial declaration that the claims of the '531 patent are invalid.

COUNT XVIII

Declaratory Judgment of Non-Infringement of the '531 Patent

147. Hetero re-alleges and incorporates by reference the allegations of paragraphs 1-146 as though fully set forth herein.

148. There is an actual, substantial, and continuing case or controversy between Hetero and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '531 patent.

149. The manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '531 patent, either literally or under the doctrine of equivalents. In particular, the claims of the '531 patent that cover pomalidomide or its use are invalid, and "invalidity operates as a complete defense to infringement for any product, forever." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) *citing Blonder–Tongue Laboratories, Inc. v. University of Illinois Foundation,* 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971).

150. As such, Hetero is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Hetero's ANDA Product described in Hetero's

ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '531 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Hetero respectfully prays for judgment in its favor and against Plaintiff/Counterclaim-Defendant:

A. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '262 patent, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the '262 patent are invalid;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '939 patent, either literally or under the doctrine of equivalents;

D. Declaring that the claims of the '939 patent are invalid;

E. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '428 patent, either literally or under the doctrine of equivalents;

F. Declaring that the claims of the '428 patent are invalid;

G. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '427 patent, either literally or under the doctrine of equivalents;

H. Declaring that the claims of the '427 patent are invalid;

I. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '720 patent, either literally or under the doctrine of equivalents;

J. Declaring that the claims of the '720 patent are invalid;

K. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '977 patent, either literally or under the doctrine of equivalents;

L. Declaring that the claims of the '977 patent are invalid;

M. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale,

imported, or marketed—infringe, either directly or indirectly, any claim of the '784 patent, either literally or under the doctrine of equivalents;

N. Declaring that the claims of the '784 patent are invalid;

O. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '886 patent, either literally or under the doctrine of equivalents;

P. Declaring that the claims of the '886 patent are invalid;

Q. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Hetero ANDA Product in Hetero's ANDA 210236 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any claim of the '531 patent, either literally or under the doctrine of equivalents;

R. Declaring that the claims of the '531 patent are invalid;

S. Ordering that Plaintiff/Counterclaim-Defendant's Complaint be dismissed with prejudice and judgment entered in favor of Hetero;

T. If the facts so demonstrate, declaring this case exceptional and awarding Hetero its reasonable attorneys' fees, expenses, and costs under 35 U.S.C. § 285, this Court's inherent authority and/or any other applicable authority;

U. Ordering that Plaintiff/Counterclaim-Defendant, and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined

from using any one or more of the Patents-in-Suit to block, hamper, hinder or obstruct FDA approval of the products described in Hetero's ANDA; and

V. Awarding such other and further relief as the Court may deem just and proper.

Dated: July 13, 2017

By: */s/ Melissa E. Flax*

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CERTIFICATE OF SERVICE

The undersigned certifies and states that a true and accurate copy of the foregoing DEFENDANTS HETERO LABS LIMITED, HETERO LABS LIMITED UNIT V, HETERO DRUGS LIMITED, AND HETERO USA, INC.S' ANSWER, DEFENSES AND COUNTERCLAIMS was caused to be filed with the Court's electronic filing system at the Office of the Clerk, United States District Court for the District of New Jersey, 402 East State Street, Trenton, New Jersey, and served on all counsel of record for Plaintiff via the Court's electronic filing system and email.

By: */s/ Melissa E. Flax*

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